| | Application No. | Applicant(s) | | | |
|---|---|--|--|--|--|
| | 10/781,965 | ROSATI, CONI F. | | | |
| Notice of Allowability | Examiner | Art Unit | | | |
| | Laura C. Hill | 3761 | | | |
| | Laura C. I IIII | 3701 | | | |
| The MAILING DATE of this communication apper All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 | (OR REMAINS) CLOSED in this app or other appropriate communication GHTS. This application is subject to | olication. If not included will be mailed in due course. THIS | | | |
| 1. A This communication is responsive to Amendments and Rel | marks filed 15 November 2005. | | | | |
| 2. The allowed claim(s) is/are <u>58-60,69-101 and 104-113</u> . | | | | | |
| 3. Acknowledgment is made of a claim for foreign priority un a) All b) Some* c) None of the: | | | | | |
| Certified copies of the priority documents have Certified copies of the priority documents have | | | | | |
| 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this national stage application from the | | | | | |
| ∴ 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * Certified copies not received: | | | | | |
| Applicant has THREE MONTHS FROM THE "MAILING DATE" on noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | | complying with the requirements | | | |
| 4. A SUBSTITUTE OATH OR DECLARATION must be submi | | | | | |
| 5. CORRECTED DRAWINGS (as "replacement sheets") mus | t be submitted. | | | | |
| (a) ☐ including changes required by the Notice of Draftspers | on's Patent Drawing Review (PTO- | 948) attached | | | |
| 1) 🗌 hereto or 2) 🔲 to Paper No./Mail Date | | | | | |
| (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date 20051206. | s Amendment / Comment or in the O | ffice action of | | | |
| Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the | | | | | |
| 6. DEPOSIT OF and/or INFORMATION about the deposit attached Examiner's comment regarding REQUIREMENT I | | | | | |
| | | | | | |
| Attachment(s) 1. ☑ Notice of References Cited (PTO-892) | 5. Motice of Informal Pr | atent Application (PTO-152) | | | |
| 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | 6. ☑ Interview Summary | | | | |
| | Paper No./Mail Date | e <u>20051108</u> . | | | |
| 3. ☑ Information Disclosure Statements (PTO-1449 or PTO/SB/06 Paper No./Mail Date 6/24/05 (λρα qe.≤) | 8), 7. 🛛 Examiner's Amendn | nent/Comment | | | |
| 4. Examiner's Comment Regarding Requirement for Deposit | 8. 🛛 Examiner's Stateme | nt of Reasons for Allowance | | | |
| of Biological Material | 9. Other | | | | |
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EXAMINER'S AMENDMENT

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An examiner's amendment to the record appears below. Should the changes

and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be

submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview

with Brian Hopkins on 6 December 2005.

The application has been amended as follows:

In Claim 58, line 7,

Please delete:

"included" and replace with --contained--

In Claim 58, line 11,

Please delete:

"is non-gas generating" and replace with --does not generate gas--

In Claim 58, line 12,

--is---

has been inserted prior to "packaged prior to use"

In Claim 100, line 8,

Please delete:

"included" and replace with -contained--

In Claim 100, line 14,

Please delete:

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"is non-gas generating" and replace with --does not generate gas--

In Claim 100, line 15,

--is--

has been inserted prior to "packaged prior to use"

In Claim 101, line 9,

Please delete:

"included" and replace with --contained--

In Claim 101, line 13,

Please delete:

"is non-gas generating" and replace with --does not generate gas--

In Claim 101, line 13

--is--

has been inserted prior to "packaged prior to use"

In Claim 104, line 7,

Please delete:

"included" and replace with --contained--

In Claim 113, line 8,

Please delete:

"is non-gas generating" and replace with --does not generate gas--

Drawings

The following changes to the drawings have been approved by the examiner and agreed upon by applicant: new formal drawings of Figures 1-6 are required. In order to

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avoid abandonment of the application, applicant must make these above agreed upon drawing changes.

Specification

The following amendment to the title has been entered and the title will be as follows: Tissue Dressing Having Gas Reservoir.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: the art of record fails to disclose or suggest a tissue dressing apparatus with one or more predetermined gases included within the reservoir, the tissue dressing apparatus is nongas generating and does not include external to the reservoir gas-releasing agents for improved wound healing. The claimed tissue dressing apparatus meets the criteria for patentability since the prior art does not disclose or fairly suggest an apparatus that contains but does not generate gases at concentrations greater than atmospheric in a reservoir without the use of an external source, which allows the tissue dressing apparatus to control the rate of gas diffusion to the wound in a continuous manner to speed wound healing and reduce infection (see Specification pages 4-6). In contrast, the following prior art discloses wound healing apparatus with external gas-generating systems not contained within a reservoir.

<u>Cantwell</u> (US 6,767,342) discloses an oxygen bandage system 10 with absorbent top and bottom layers 12, 14 having pressure sensitive capsules 20a-20d containing hydrogen peroxide 17 embedded within. Cantwell further discloses pressure must be applied to the capsules so that the hydrogen peroxide is released and

saturates first absorbent layer 12, said hydrogen peroxide then reacts with potassium manganese catalyst film 24 to cause the release of oxygen that moves through second absorbent layer 14 and contacts the wound for healing (column 3, figures 3 and 6). Cantwell does not disclose or suggest that one or more predetermined gases is contained within the reservoir or that the apparatus is non-gas generating.

Ladin (US 5,792,000) discloses a tissue dressing system that requires the addition/renewal of hydrogen peroxide added to oxygen supply reservoir 105 to generate oxygen during use to simulate hyperbaric conditions (column 5, line 51-column 6 line 5 and column 8, lines 18-42). Ladin does not disclose or suggest that the reservoir contains one or more predetermined gases since gas is generated as a result of the hydrogen peroxide reaction.

<u>Cantwell</u> (US 6,000,403) discloses a hyperbaric bandage with oxygen emanating from the reaction of hydrogen peroxide and any other biologically acceptable reducing metal catalyst, said oxygen *not contained within* any reservoir (column 2, lines 12-34). Cantwell does not disclose or suggest that the reservoir contains one or more predetermined gases since gas is generated as a result of the hydrogen peroxide *reaction*.

Argenta et al. (US 2001/0029956) discloses a wound treatment apparatus for treating wounds that *applies reduced pressure* rather than gas at concentrations greater than atmospheric *via an external source* so suction may be applied to wound site for a controlled period of time (page 3, paragraph 0028). Argenta does not disclose or suggest that the reservoir contains one or more predetermined gases being applied.

Scherson (US 5,578,022) discloses an oxygen regulator, which *generates* oxygen according to an electrochemical process driven by an internal or external power source and subsequently supplies it to a skin wound for healing (column 2, lines 22-53). Scherson does not disclose or suggest an apparatus that does not generate gas.

<u>Swenson et al.</u> (US 6,113,922) discloses compositions that provide pressures of carbon dioxide in a wound treatment apparatus via chemical reaction and is thus *gas* generating.

The following prior art references do not generate gas but comprises *non-gaseous materials* contained within a reservoir to promote wound healing are as follows:

Eckert et al. (US 5,487,889) discloses biological bandage 10 having a top gas permeable membrane 14, polyethylene bottom membrane 15 and *cellular growth factor* product 17 (not a gas) contained within chamber 56 to increase the rate of wound healing (column 3, lines 15-52).

Augustine (US 5,964,721) discloses a wound covering 50 with peripheral sealing ring 52 to be attached to uninjured skin surrounding the wound area 54 using an adhesive 56 (column 3, lines 35-40. Augustine further discloses the sealing ring 52 serves as a reservoir for retaining water or medicaments in a treatment volume pocket 62 or in an alternative embodiment treatment volume 112 is supplied with heat and gases via an external source 18 (column 5, lines 43-52).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura C. Hill Examiner Art Unit 3761

TATYANA ZALUKAEVA SUPERVISORY PRIMARY EXAMINER

Gavents

LCH

DATE MAILED:



U.S. Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450

Alexandria, Virginia 22313-1450

| APPLICATION NO.J CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | | ATTORNEY DOCKET NO. |
|---------------------------------|-------------|--|----------|---------------------|
| | | | EXAMINER | |
| | | | ART UNIT | PAPER |
| | | | | 20051206 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents